REMARKS

Claims 31, 32, 35-40, 42-44, 46-49 and 53-59 currently appear in this application. The Office Action of November 17, 2005, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed.

Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Interview

Applicant's attorney wishes to thank Examiner Gollamudi for the courtesies extended during the personal interview of March 20, 2006. During that interview, Examiner Gollamudi indicated that reciting the amount of cellulose in the tablet may overcome the prior art and show unexpected results.

Art Rejections

Claims 31, 32, 36 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al., US 6,423,754. The Examiner alleges that the specific gravity and properties are inherent in Holmes-Farley since Holmes-Farley use the same solvent mixture as applicants. The Examiner

concedes that Holmes-Farley does not exemplify the tablet formulation.

This rejection is respectfully traversed. Holmes-Farley never discloses the combination of the phosphate-binding polymer and microcrystalline cellulose in a tablet, nor, particularly, the amount of microcrystalline cellulose in a tablet containing phosphate-binding polymer. There is only fleeting reference to tablets at column 17, lines 37-38. However, there is nothing in Holmes-Farley about the inherent stickiness of phosphate-binding polymers and the difficulties experienced in formulating them into tablets.

The claims presently recite that there is at least 10% microcrystalline cellulose or hydroxypropyl cellulose present in the tablet. This amount of cellulose component makes it possible to prepare a tablet that is not sticky and can be swallowed easily. Which is of particular importance for patients undergoing dialysis, who are permitted to have only limited amounts of liquid.

Battista, US 4,146,168, was cited as disclosing that microcrystalline cellulose is less tacky and sticky. It is respectfully submitted that Battista does not disclose the same microcrystalline cellulose used in the present formulations, but rather discloses "aggregates." These aggregates are prepared from any of the natural cellulose

materials, such as natural fibers, purified wood pulp, or regenerated forms of cellulose by the controlled acid hydrolysis of the cellulosic materials to reduce the molecular weight of the cellulosic materials to obtain small, disintegrated aggregates. The level-off D.P. value reflects a destruction of the original fibrous structure of the cellulosic source material, as disclosed at column 1, line 53 to column 2, line 35 of Battista.

These small disintegrated aggregates are not at all the same as the microcrystalline cellulose used herein. Tablets formulated with these aggregates have poor disintegration properties. However, tablets of phosphate-binding polymers made with microcrystalline cellulose have excellent disintegration properties. Battista at column 11, lines 53-68, note that the incorporation of aggregates greatly slows down the disintegration time of tablets. This is the opposite of the effect of the microcrystalline cellulose. Therefore, it is respectfully submitted one skilled in the art would have no motivation to use the aggregates of Battista in formulating tablets of phosphate-binding polymer, since these tablets must disintegrate rapidly in order to bind phosphate ions.

In addition to the disintegration properties of tablets, applicants would also like to refer to the stickiness

of tablets containing an excipients. One of the inventors of the present application demonstrated in a Declaration Under 37 CFR 1.132, signed by him February 16, 2005, that an excipient other than microcrystalline cellulose and low substituted hydroxypropyl cellulose was not capable of reducing the stickiness of tablets contains phosphate-binding polymers, even though the tested excipients, such as hydroxypropyl cellulose or hydroxypropylmethyl cellulose, are similar to microcrystalline cellulose with respect to chemical structure and raw material.

This declaration shows that it is difficult or impossible to predict whether an excipients will be appropriate to reduce the stickiness of phosphate-binding polymer containing tablets, even though the structure of the two excipients is very close.

The phosphate-binding polymers claimed herein are very sticky, and they must be taken in a relatively large single dose, such as from 1 to 2 grams (see page 3, lines 21-22 of the present specification). Patients on dialysis who require the phosphate-binding polymer as treatment for hyperphosphatemia are often limited in the amounts of water they are allowed to ingest (page 4, lines 2-5 of the specification), and patients to be treated include a high proportion of elderly persons, who tend to have difficulty

swallowing tablets (page 2, lines 11-13 of the declaration signed February 16, 2005). As stated in the description from page 4, line 27 to page 5, line 2, special attention should be paid to preparing tablets with a high content of the active component. That is, it was recognized in the art prior to the present application that the stickiness of the phosphate-binding polymer must be reduced by using the smallest amount of excipients possible.

Battista describes in column 5, lines 66-74, that under conditions of increasing humidity, starch becomes tacky or sticky, whereas the aggregates do not. However, there are no specific data provided with respect to the specific amounts or proportions of the aggregates required to reduce stickiness.

It is respectfully submitted that one skilled in the art could not predict whether the use of the aggregates of Battista could reduce the stickiness of tablets containing a high proportion of phosphate-binding polymer, which is a very sticky substance. Moreover, there is neither disclosure nor suggestion in Battista of providing at least 10% of cellulose component in the tablets.

Claims 34-35, 39-40, 42-46, 49 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al. in view of Chen et al., US 5,225,204.

This rejection is respectfully traversed. Chen has absolutely nothing to do with Holmes-Farley in preparing non-sticky tablets of phosphate-binding polymers. Chen is concerned with producing stable dosages of levothyroxine sodium, which is hygroscopic and degrades rapidly under conditions of high humidity. There is nothing in Chen about the stickiness of levothyroxine sodium. Chen mixes a commercial grade of levothyroxine sodium with polyvinylpyrrolidone and at least partially dissolves the mixture in a polar organic solvent. Chen then adds a cellulose carrier component such as microcrystalline cellulose. The solvent components of the solution or mixture are removed by drying to form a stable powder of levothyroxine sodium and PVP dispersed on the surface of the cellulose carrier component. (column 1, lines 36-64)

Chen solves a very different problem from making non-sticky tablets of phosphate-binding polymers. One skilled in the art would have no reason to use the microcrystalline cellulose of Chen with the phosphate-binding polymers of Holmes-Farley.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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